



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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November 19, 1998

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

WARNING LETTER

CHI-5-99

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Mr. Theodore Mantas, President/Owner  
Helmos Food Products  
159-167 South Water Market  
Chicago, Illinois 60608

Dear Mr. Mantis:

Inspection of your firm by the U.S. Food and Drug Administration (FDA) on July 28-31, August 26, and September 4, 8, and 9, 1998, documented numerous insanitary conditions at your food storage warehouse which caused the stored food products to become adulterated. The inspections were conducted at the request of the U.S. Department of Agriculture, Food Sanitation and Inspection Service (FSIS), following their reported finding of extensive rodent activity at this location which stores meat, poultry and FDA regulated products. This letter refers to our findings concerning FDA regulated products only.

Our inspection showed that food products stored and held at your facility were found adulterated. These adulterated food products are in violation of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). These adulterated food products: a) consisted in whole or in part of filthy substances, such as rodent fecal pellets and rodent hairs; and b) had been held under insanitary conditions whereby they have become contaminated with rodent filth.

Evidence of rodent activity in the form of live rodents (mice), excreta pellets, and dead and recently killed mice, were observed on the first floor, including the cooler. Evidence of rodent gnawed cheese and margarine containers were observed. Scores of rodent excreta pellets and rodent nesting material were observed on a stainless steel table, cheese products, and pallets in all areas of the first floor.

Dock doors leading to the exterior of the building were observed open during most of the inspections. When closed they were not tight fitting. There were openings up to four inches wide by one inch high. Other avenues of entrance/egress observed included holes in walls and ceilings and uncovered floor drains.

Our laboratory confirmed the findings of rodent excreta and rodent hair sampled from the warehouse during the inspection.

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The above listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence with each requirement of the Federal regulations. The Investigators reported you have destroyed lots of dry foods and cartons of cheese and margarine that showed evidence of rodent gnawing and began to take some steps to correct the insanitary conditions in your facility. We request that you take prompt action to correct all violations.

Please provide this office in writing, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take and have taken to correct and prevent the recurrence of these objectionable conditions. Provide the time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to Paul A. Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

/s/  
Raymond V. Mlecko  
District Director